net work in Madhya Pradesh during the Seventh Five Year Plan period; and

(b) the names of the railway lines in Madhya Pradesh and alongwith their total length that are proposed to be electrified during this period?

THE MINISTER OF STATE IN THE MINISTRY OF RAILWAYS (SHRI MADHAVRAO SCINDIA): (a) Details of the new rail lines partly or fully in Madhya Pradesh included in Railway Budget are as under:—

S. No.	New Lines	Length (Kms.)	Estimated Cost (in crores)
1	Kota-Chittaurgarh-Neemuch . . .	222	97·87
2	Guna-Shivpuri-Gwalior-Etawah . . .	348	158.77
3	Satna-Rewa	50	45·83

(b) Following Railway lines falling in Madhya Pradesh are proposed to be progressed for electrification dur ing the 7th Five Year Plan period:—

	Route	Section	Route Kms.
1	Delhi-Bombay *via* Central Rly. Route	(1) Hetampur-Gwalior-Datia.	125
		(2) Dhaura-Itarsi . . .	265
		(3) Itarsi-Burhanpur . .	257
2	Delhi-Bombay *via* Western Rly. Route	(1) Ratlam-Nahargarh . .	
		(2) Thuria-Ratlam . . .	100
		(3) Pach-Pahar-Nathukheri .	49
3	Itarsi-Nagpur .	(1) Itarsi-Darimeta . . .	205
4	Champa-Garwa Road	Champa-Garwa Road .	45
5	Durga-Nagpur	Durga-Bortalao . .	79

Marketing permission for New Drugs

2125. SHRI RAJNI RANJAN SAHU: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to refer to the answer to Unstarred Question 247 given in the Rajya Sabha on the 5th November, 1986 and state:

(a) whether it is a fact that marketing permission for new drugs and new combination of drugs is required from Drugs Controller, India;

(b) whether it is also a fact that marketing and manufacturing permissions are being granted by State Drug Authorities;

(c) if so, the details thereof;

(d) whether it is a fact that State Drug Authorities are granting permission without clinical trials and published dates on combination of drugs;

(e) whether it is also a fact that there are a number of irrational combination of drugs available in the country as a result thereof;

(f) if so, what steps are being taken by Government to solve the problem; and

(g) the names of combination of drugs cleared by Government without clinical trials alongwith the reasons of clearance in each case during the last three years?

THE MINISTER OF STATE IN THE DEPARTMENT OF HEALTH IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (KUMARI SAROJ KHAPARDE): (a) Yes, Sir.

(b) and (c) Under the provisions of the Drugs and Cosmetics Act, State Drugs Control Authorities are the licensing authorities for manufacture and sale of drugs.

(d) It has been brought to the notice of the Government that State Drugs Controllers some times grant permission of drugs without insisting on clinical trials but based on published data and experts' advice. Appendix 7 of the Guidelines on Introduction of New Drugs stipulates that for combnation whose individual active ingredient which have been wedely used for years and where concomitant use is considered necessary, clinical trials are not generally required for such combination provided such a combination has an acceptable rationale.

(e) and (f) The question of rationality of combinations of drugs is being monitored in context of the latest scientific knowledge by a Sub-Committee constituted by Drugs Consultative Committee which recommends from time to time weeding out of irrationale/harmful drugs moving in the market. Based on the recommendations and in exercise of the power acquired under the amended Drugs and Cosmetics Act, Government prohibits the import/manufacture and sale of irrationale/harmful formulations through Notification from time to time. So far Government have prohibited the import, manufacture and sale of 26 categories of drugs/drug combinations.

(g) Names of combinations drugs cleared by the Drugs Controller (India) without clinical trials along with the reasons is given in the enclosed statement.

Statement

Names of combinations of drugs cleared by Drugs Controller (India) during the last three year without Clincial trials along with the reasons

Name of the combination	Rationale
1 Frusemide with Spironolactone Tablets/Capsules	The concomitant use of both the drugs was considered necessary by experts as potassiumloss due to Fursemide is compensated by Spironolactone.
2. Metoclopramide with Dimethylopolysiloxane Tablets	Metoclopramide a broad sepectrum antinauseant normalizes the gastric stasis and gastric emptying time. In such clincal situation there is generally associated formation of gas adding to the discomfort of the patients. Concomitant use of polysiloxane absorbs the gas in the instestime. The combination is backed by a sound rationale.
3. Levodopa with Benserazide capsules	The combination was allowed on the published evidence of advantages of combining Benserazide, a decarboxylase inhibitor with Levodopa as the former reduces the dose of Levodopa by about 75% and the

Name of the combination	Rationale
	side effects of Levodopa are markedly eliminated. The combination facilitates reaching the effective level of Levodopa in the brain, the diurenal variations in control of symptoms by Levodopa are reduced by concomitant use of Benserazide and percentage of patients improved with the combination is more than with levodopa alone.
4 Levamisole with Mebendazole Tablets.	The concomitant use of both the drugs was considered necessary by experts for mixed infections of thread worm and round worm.
5. Tinidazole with Diloxanide Fuorate Tablets	The combination was cleared on the rationale that while Diolocanide is a specific locally acting anti-amoebic drug, Tinidazole is a systemic anti-amoebic and therefore a concomitant use takes care of both intestinal and extra-intestinal amoebiasis.
6. Ibueprofen with Paracetamol Tablets	While Ibueprofen is more of a anti-inflammatory and anti-rheumatic drug, Paracetamol alleviates the pain associated with inflammation. The experts consulted opined that such a combination would be useful. It is marketed in developed countries.
7. Acebutolol Hydrochloride with Hydrochlorothiazide Tablets .	Acebutolol, a beta-blocker and Hydrochlorothiazide a diuretic are allowed to be marketed in the country. Permission to market the combination was granted as the experts considered that very often combination of a beta-blocker and a diuretic is a therapeutic necessity and for better compliance their concomitant use should be allowed.
8. Betamethasone Dipropionate with Betamethasone Sodium Phosphate Injection	Both are salts/ester of Betamethasone and the combination is backed by a sound rationale to the effect that while one acts immediately the other by virtue of longer duration of action maintains the desired effects.

Monitoring of dangerous side effects of drugs

2126. SHRI RAJNI RANJAN SAHU: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) what arrangements have been made by Government for monitoring the dangerous side effects of drugs and combination of drugs;

(b) what is the set up of such cell and the details of authority who is incharge;

(c) the names of drugs and combination of drugs whose dangerous effects have come to Government's notice since last two years;

(d) whether any of those drugs have been banned;

(e) if so, the details thereof;

(f) whether Government are aware of the number of reports regarding dangerous effects of combination of Aspirin, Paracetamol with Anti-histamine published through-out the world; and